

## Complete Summary

---

### GUIDELINE TITLE

Practice management guidelines for prophylactic antibiotic use in open fractures.

### BIBLIOGRAPHIC SOURCE(S)

Practice management guidelines for prophylactic antibiotic use in open fractures.  
Allentown (PA): Eastern Association for the Surgery of Trauma (EAST); 2000. 28  
p. [69 references]

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY

## SCOPE

### DISEASE/CONDITION(S)

Open fractures

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness  
Management  
Prevention

### CLINICAL SPECIALTY

Emergency Medicine  
Orthopedic Surgery  
Surgery

### INTENDED USERS

Advanced Practice Nurses  
Allied Health Personnel  
Nurses

Physician Assistants  
Physicians

#### GUIDELINE OBJECTIVE(S)

To present recommendations for prophylactic antibiotic usage for open fractures.

#### TARGET POPULATION

Individuals with open fractures

#### INTERVENTIONS AND PRACTICES CONSIDERED

1. Preoperative antibiotic prophylaxis
  - Penicillin and penicillin derivatives (dicloxacillin, benzyl penicillin, methicillin, oxacillin, ampicillin, nafcillin, ticarcillin, cloxacillin)
  - Cephalosporins (cephalothin, cefazolin, cephradine, cefonicid, cefamandole, cephalexin, ceftriaxone)
  - Aminoglycosides (tobramycin, streptomycin, garamycin, gentamicin, kanamycin)
  - Clindamycin
  - Erythromycin
2. Single versus combination antibiotic therapy
3. High-dose penicillin
4. Duration of antibiotic therapy (24 hours versus more than 24 hours)
5. Use of wound cultures to direct choice of therapy
6. Route of antibiotic delivery
  - Intravenous
  - Antibiotic-impregnated beads (polymethyl methacrylate [PMMA] beads)
7. Wound debridement and wound irrigation
8. Type of closure (primary versus delayed)

#### MAJOR OUTCOMES CONSIDERED

Incidence of infection, including superficial and deep infections and osteomyelitis.

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Articles were identified from the literature by independent searches performed by two of the reviewers. One search was performed using OVID MEDLINE and covered the literature from 1985 to 1997. Key words used in this search were "open fracture, antibiotics, prophylaxis, and management". References from 1975

to 1985 were identified through a MEDLINE search using the following key words: "antibiotic prophylaxis; human; open fractures; bacterial infections - prevention and control; fracture healing; fracture-complications; and surgical wound infections". These combined searches identified 313 articles. The bibliography of each article was reviewed for additional references, which were not identified in the two original searches. Letters to the editors, case reports, and review articles were excluded from further evaluation. This identified 56 studies for evidentiary review.

#### NUMBER OF SOURCE DOCUMENTS

56 source documents.

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Classification Scheme:

Class I: Prospective, Randomized, Double-Blinded Study

Class II: Prospective, Randomized, Non-Blinded Trial

Class III: Retrospective Analysis of Patient Series

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

#### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Articles retrieved from the literature search were reviewed by 3 orthopedic trauma surgeons, 2 general surgeons, and two pharmaceutical outcome researchers with interest in pharmacokinetics and health care economics. These individuals then collaborated to produce the guideline recommendations.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level I: This recommendation is convincingly justifiable based on the available scientific information alone. It is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory Class I data may not be able to support a level 1 recommendation.

Level II: This recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert critical care opinion. It is usually supported by Class II data or a preponderance of Class III evidence.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document is submitted to all members of the panel for review and modification. Subsequently the guidelines are forwarded to the chairmen of the Eastern Association of Trauma ad hoc committee for guideline development. Final modifications are made and the document is forwarded back to the individual panel chairpersons.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Level I and II recommendations, and the class of data grading (I-III) are defined at the end of the "Major Recommendations" field.

Multiple studies have documented the reduction in wound infections with the use of prophylactic antibiotics in the care of patients with open fractures. Although studies with various therapeutic agents have suggested an improved outcome with prolonged (greater than 24 hours) therapy, none have been done with appropriate controls. The most difficult open fracture wound to care for is the Grade IIIb tibial fracture (see "Classification of Open Fractures", below). Although some authors advocate application of antibiotic impregnated beads for local control of infection in addition to parenteral administration, supportive Class I and II data are not available. These wounds (type III) should receive coverage for gram-negative organisms in addition to gram-positive coverage.

### Classification of Open Fractures

Grade (Type) I: Open fracture with a skin wound less than 1 cm long and clean.

Grade (Type) II: Open fracture with a laceration more than 1 cm long without extensive soft tissue damage, flaps, or avulsions.

Grade (Type) III: Either an open segmental fracture, an open fracture with extensive soft tissue damage, or a traumatic amputation.

#### Grade III Stratification

IIIa: Adequate soft tissue coverage of a fractured bone despite extensive soft tissue laceration or flaps, or high energy trauma irrespective of the size of the wound.

IIIb: Extensive soft tissue injury loss with periosteal stripping and bone exposure, usually associated with massive contamination.

IIIc: Open fractures associated with arterial injury requiring repair.

#### A. Level I Recommendations

There are sufficient Class I and II data to recommend preoperative dosing with prophylactic antibiotics (as soon as possible after injury) for coverage of gram positive organisms as optimum care for trauma patients with open fractures. For Grade III fractures, additional coverage for gram-negative organisms should be given. High-dose penicillin should be added to the antibiotic regimen when there is a concern for fecal/Clostridial contamination such as in farm related injuries.

#### B. Level II Recommendations

There are sufficient Class I and Class II data to recommend antibiotics be discontinued 24 hours after wound closure for Grade I and II fractures. For Grade III wounds, the antibiotics should be continued for only 72 hours after the time of injury or not more than 24 hours after soft tissue coverage of the wound is achieved, whichever occurs first.

#### Definitions:

##### Recommendation Scheme:

Level I: This recommendation is convincingly justifiable based on the available scientific information alone. It is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory Class I data may not be able to support a level 1 recommendation.

Level II: This recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert critical care opinion. It is usually supported by Class II data or a preponderance of Class III evidence.

##### Classification Scheme:

Class I: Prospective, Randomized, Double-Blinded Study

Class II: Prospective, Randomized, Non-Blinded Trial

Class III: Retrospective Analysis of Patient Series

#### CLINICAL ALGORITHM(S)

None provided

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Conclusions were based on evidence obtained from prospective, randomized, double-blinded studies (Class I); prospective, randomized, non-blinded studies (Class II); or retrospective analysis or patient series (Class III). The evidentiary table included 10 class I, 8 Class II, and 36 Class III references.

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Reduction in the rate of wound infections in patients with open fractures.

Subgroups Most Likely to Benefit:

Individuals with grade III fractures

#### POTENTIAL HARMS

Not stated

### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

The guideline developers make the following recommendations regarding implementation:

Implementation involves extensive education and inservicing of nursing, resident, and attending staff members and has one important guiding principle: the guidelines must be available to the clinicians in real time while they are actually seeing the patient. The two most common ways to apply these are by using either a critical pathway or a clinical management protocol. A critical pathway is a calendar of expected events that has been found to be very useful within

designated diagnosis-related groups. In trauma, where there are multiple diagnosis-related groups used for one patient, pathways have not been found to be easily applied with the exception of isolated injuries. Clinical management protocols, on the other hand, are annotated algorithms that answer the "if, then" decision making problems and have been found to be easily applied to problem-, process-, or disease-related topics. The clinical management protocol consists of an introduction, an annotated algorithm and a reference page. The algorithm is a series of "if, then" decision making processes. There is a defined entry point followed by a clinical judgment and/or assessment, followed by actions, which are then followed by outcomes and/or endpoints. The advantages of algorithms are that they convey the scope of the guideline, while at the same time organize the decision making process in a user-friendly fashion. The algorithms themselves are systems of classification and identification that should summarize the recommendations contained within a guideline. It is felt that in the trauma and critical care setting, Clinical management protocols may be more easily applied than critical pathways, however, either is acceptable provided that the formulated guidelines are followed. After appropriate inservicing, a pretest of the planned guideline should be performed on a limited patient population in the clinical setting. This will serve to identify potential pitfalls. The pretest should include written documentation of experiences with the protocol, observation, and suggestions. Additionally, the guidelines will be forwarded to the chairpersons of the multi-institutional trials committees of the Eastern Association for the Surgery of Trauma, the Western Association for the Surgery of Trauma, and the American Association for the Surgery of Trauma. Appropriate guidelines can then be potentially selected for multi-institutional study. This process will facilitate the development of user friendly pathways or protocols as well as evaluation of the particular guidelines in an outcome based fashion.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Practice management guidelines for prophylactic antibiotic use in open fractures. Allentown (PA): Eastern Association for the Surgery of Trauma (EAST); 2000. 28 p. [69 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

2000

#### GUIDELINE DEVELOPER(S)

Eastern Association for the Surgery of Trauma - Professional Association

#### SOURCE(S) OF FUNDING

Eastern Association for the Surgery of Trauma (EAST)

#### GUIDELINE COMMITTEE

EAST Practice Management Guidelines Work Group

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Fred A. Luchette, MD; Lawrence B. Bone, MD; Christopher T. Born, MD; William G. DeLong, Jr., MD; William S. Hoff, MD; C. Daniel Mullins, PhD; Francis Palumbo, PhD, JD; Michael D. Pasquale, MD

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

#### GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF] format) from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#).

Print copies: Available from the EAST Guidelines, c/o Fred A. Luchette, MD, Loyola University Medical Center, Department of Surgery Bldg. 110-3276, 2160 S. First Avenue, Maywood, IL 60153; Phone: (708) 327-2680; E-mail: fluchet@lumc.edu.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Practice Management Guidelines for Trauma: East Ad Hoc Committee on Guideline Development (Unabridged: Revised 1998 Mar 20). Available from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#).



An excerpt is also available:

- Pasquale M, Fabian TC. Practice management guidelines for trauma from the Eastern Association for the Surgery of Trauma. J Trauma 1998 Jun;44(6):941-56; discussion 956-7.

Also available:

- Utilizing evidence based outcome measures to develop practice management guidelines: a primer. Allentown (PA): Eastern Association for the Surgery of Trauma; 2000. 18 p. Available from the [EAST Web site](#).

Print copies: Available from the EAST Guidelines, c/o Fred A. Luchette, MD, Loyola University Medical Center, Department of Surgery Bldg. 110-3276, 2160 S. First Avenue, Maywood, IL 60153; Phone: (708) 327-2680; E-mail: fluchet@lumc.edu.

#### PATIENT RESOURCES

None available

#### NGC STATUS

This summary was completed by ECRI on March 9, 2001. The information was verified by the guideline developer on May 4, 2001.

#### COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the Eastern Association for the Surgery of Trauma (EAST).

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/15/2004

**FIRSTGOV**

